AWARD NUMBER:

W81XWH-11-1-0641

TITLE:

Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

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REPORT DATE: December 2017

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
December 2017	Final	15Sep2011 - 14Sep2017
4. TITLE AND SUBTITLE		5a. CONTRACT NUMBER
Enhanced Cognitive Rehabi	ilitation to Treat Comorbid TBI and PTSD	
		5b. GRANT NUMBER
		W81XWH-11-1-0641
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)		5d. PROJECT NUMBER
Amy Jak		5e. TASK NUMBER
		Se. PASK NOWIDER
E-Mail: ajak@ucsd.edu		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
Veterans Medical Research	Foundation	NOMBER
3350 La Jolla Village Driv		
San Diego, CA 92161	C (131A)	
Ball Blego, ca 72101		
9. SPONSORING / MONITORING AGENCY	NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
U.S. Army Medical Research and M	lateriel Command	
•		11. SPONSOR/MONITOR'S REPORT
Fort Detrick, Maryland 21702-5012		NUMBER(S)
40 DICTRIBUTION / AVAIL ADJUTY CTAT		

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This was a randomized controlled treatment study to test a modification of Cognitive Processing Therapy (CPT) for PTSD in which CPT is interwoven with compensatory cognitive rehabilitation principles (CogSMART) to create a hybrid treatment, SMART-CPT. The study examined 100 veterans diagnosed with both PTSD and a history of mild to moderate TBI and randomized half to receive standard CPT and half to receive SMART-CPT for 12 weekly sessions. Veterans also received comprehensive symptom, mental health, and neuropsychological assessments at 3 time points during the study. The investigation sought to improve treatment outcomes for combat-related psychological health and develop an evidence-based intervention for treatment of comorbid TBI and PTSD.

15. SUBJECT TERMS

TBI, PTSD, cognitive rehabilitation, CPT

16. SECURITY CLASSIFICATION OF:		17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC	
a. REPORT	b. ABSTRACT	c. THIS PAGE	UU	14	19b. TELEPHONE NUMBER (include area code)
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INTRODUCTION:

This study focused on helping Iraq and Afghanistan Veterans who have a history of mild to moderate traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) benefit fully from interventions for both conditions. PTSD and TBI occur together frequently in Iraq and Afghanistan Veterans, a combination of conditions which often complicates recovery from either condition. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mild to moderate TBI can impede recovery from PTSD. Prior research has shown that cognitive rehabilitation programs that focus on teaching about what is typical after a TBI, providing people with expectation of positive recovery, and teaching strategies that allow individuals to compensate for their cognitive deficits are effective for treating the thinking symptoms resulting from mild to moderate TBI. These practice standards have been organized into a manualized treatment, Cognitive Symptom Management and Rehabilitation Therapy (CogSMART), which teaches Veterans ways to compensate for cognitive difficulties. Psychotherapies that focus on changing thoughts and behaviors related to a traumatic event, such as Cognitive Processing Therapy (CPT), are effective treatments for PTSD and are the standard of care for treatment of the disorder. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this randomized controlled trial integrated therapeutic approaches and tested a modification of CPT in which CPT was enhanced with compensatory cognitive rehabilitation principles detailed in CogSMART. The enhanced CPT, called SMART-CPT was compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mild to moderate TBI and current PTSD.

BODY:

The first fiscal year of the Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD study began on September 15, 2011. The study continued for a total of 6 fiscal years, ending on September 14, 2017. During the duration of the study, research accomplishments remained largely on target as outlined in the Statement of Work.

The following are accomplishments as outlined in the Statement of Work:

Task 1. Study Start Up, Months 1-12: Complete.

1a. Obtain regulatory approvals:

Initial approvals from the UCSD IRB and the VA Research and Development (VA R&D) committee were acquired. All necessary regulatory renewals and approvals were maintained and kept up-to-date during the duration of the study.

1b. Hire and train study staff:

The study coordinator, research assistants, graduate student researcher, and psychologist were hired in the first fiscal year. They promptly completed necessary VMRF and VA training in research ethics, safety and information security training, sexual harassment prevention training, and other required courses. The psychologist received training for CogSMART and the hybrid

treatment, SMART-CPT. The other staff were trained and approved on administration and scoring of the neuropsychological battery. All staff hired throughout the study remained up-to-date with all required training and approvals.

1c. Initial recruitment:

Recruitment efforts started during the first fiscal year of the study and continued through the fifth fiscal year. Recruitment activities included exchanging recruitment material with other study coordinators, placing brochures in VA clinics, utilizing the VA electronic board advertisement, maintaining contact with VA clinicians who provided referrals, utilizing an interest form in the Polytrauma clinic, and continually working with other research coordinators for referrals.

Task 2. Recruitment, Enrollment and Treatment and Assessment, months 13-40, extended with a one year no-cost extension through month 60:

2a. Ongoing recruitment of participants:

Recruitment continued as described above through fiscal year 5. See table below for final enrollment numbers.

Final Recruitment and Enrolment:

Total Referrals	Enrolled	Withdrew	Declined/Do not qualify		
564	107	57	457		

2b. Treatment:

A total of 107 participants were enrolled in the study over the course of the first 5 fiscal years. Of these, 1 was a pilot participant and was not included in final analyses, four were withdrawn after enrollment as further assessment revealed they did not meet all inclusion criteria, and two individuals enrolled but never presented for baseline assessment. Therefore, 51 participants were randomized to the SMART-CPT condition and 49 to the standard CPT treatment group. 53 participants completed all 12 treatment sessions. Fidelity checks revealed good treatment fidelity.

2c. Assessment:

105 participants completed the baseline assessment, 50 completed the immediate post-therapy assessment, and 38 completed the three-month post-therapy assessment and, therefore, completed all aspects of the protocol. All assessments were double-scored and double-entered into the database to insure accuracy in administration, scoring, and data entry.

Task 3. Data analysis, presentation, publication, months 60-72:

3a. Data Analysis:

Initial analyses used t-tests and chi-square analyses to examine whether treatment groups differed on baseline demographic variables, TBI injury variables, previous treatment history, symptom measures, and performance validity. In order to compare groups on neuropsychological measures at baseline, t-tests as well as ANCOVAs were employed with TOMM trial 2 as a covariate to control for effort. We also examined whether groups differed in rates of treatment completion and number of sessions attended using chi-square and t-tests. Initial analyses also used t-tests and chi-square analyses to examine whether those who completed the full twelve treatment sessions differed on baseline demographic variables, TBI injury variables, previous treatment history, symptom measures, and performance validity from those who did not complete all treatment sessions.

For the outcome measures of interest, data were analyzed using multilevel modeling (MLM). For the primary outcome of PTSD symptoms, all available PCL-S data from pretreatment to follow-up (15 possible time points) were used. Because those who completed treatment versus those who dropped out differed in baseline PTSD and post-concussive symptom severity, these scores were entered as covariates into the MLM predicting change in PCL-S scores at the 14 time points after baseline (starting at treatment session 1 and going through the follow-up assessment). Separate models tested each additional outcome measure of interest and included all available data (4 possible time points for NSI, 3 possible time points for BDI-II, OOLI-B, and all neurocognitive measures). Each MLM model included a random intercept and fixed effects of time, treatment group, treatment group x time interaction, as well as baseline PTSD and post-concussive symptom scores as covariates. Only the model predicting change in post-concussive symptoms did not include baseline NSI scores because they were included in the DV. TOMM trial 2 scores were also included as a covariate in models predicting changes in neuropsychological measures in order to control for effort. Finally, t-tests were used to compare groups on their treatment satisfaction, as measured by the CSQ. Results were considered significant at the level of p<.05. All analyses were conducted in SPSS version 23.0.

Results

Data is presented on 100 randomized Veterans enrolled in the study and completed baseline testing. 49 were randomized to the CPT-C condition and 51 to the SMART-CPT condition. There were no significant differences between groups on demographic factors, injury variables, symptom measures, neuropsychological measures, or rates of prior treatment at baseline (see Table 1), indicating that randomization was effective. 56.9% of the SMART-CPT group and 49% of the CPT-C group completed treatment (i.e., completed all 12 treatment sessions), though this difference was not statistically significant, $\chi^2 = .62$, p = .548. Groups also did not differ in number of sessions attended, t(98) = -1.23, p = .222. No demographic differences between completers (n = 53) and non-completers (n = 47) were observed (all ps > .34). However, non-completers had significantly higher baseline PCL-S, t(96) = -2.76, p = .007, and NSI, t(96) = -3.66, p < .001, scores than completers.

Table 1. Mean (SD) or percentage for demographic, clinical, and baseline assessment characteristics

	Total Sample	CPT	SMART-CPT	t, χ^2 , or F (df)	p	
	(N=100)	(N=49)	(N=51)			
Age, years	34.39 (7.89)	33.94 (7.27)	34.82 (8.50)	56 (98)	.578	
Education, years	13.69 (1.83)	13.88 (1.65)	13.51 (1.98)	1.00 (98)	.317	
Male, %	89.0%	87.8%	90.2%	$\chi^2 = .15 (1)$.758	
Non-Caucasian, %	53%	59.2%	47.1%	$\chi^2 = 1.48 (1)$.155	
Loss of Consciousness, minutes ^a	4.50 (8.84)	5.49 (8.90)	3.61 (8.78)	1.05 (95)	.297	
Number of TBIs	2.81 (1.92)	2.90 (1.99)	2.73 (1.87)	.44 (97)	.661	
Percentage Service Connection	57.10 (38.70)	56.73 (37.88)	57.45 (39.84)	09 (98)	.927	
Treatment						
Treatment Completion, %	53.0%	49.0%	56.9%	$\chi^2 = .62 (1)$.548	
Prior PTSD Treatment, %	57.0%	55.1%	58.8%	$\chi^2 = .14 (1)$.840	
Prior Cognitive Rehabilitation, %	1.0%	2.1%	0%	$\chi^2 = 1.03 (1)$.495	
Total sessions completed	7.96 (4.74)	7.37 (4.95)	8.53 (4.51)	-1.23 (98)	.222	
Average time per session, minutes	79.58 (19.19)	72.64 (16.20)	85.96 (19.65)	-3.57 (92)	.001	
Symptom Severity						
PCL-S	59.35 (10.65)	61.06 (9.92)	57.63 (11.17)	1.61 (96)	.111	
NSI	46.56 (14.12)	48.61 (14.92)	44.51 (13.10)	1.45 (96)	.151	
BDI-II	27.68 (10.27)	27.29 (9.62)	28.06 (10.96)	37 (95)	.714	
Cognitive b						
WRAT Reading	97.02 (10.00)	97.08 (10.63)	96.96 (9.44)	F=.27 (1,95)	.603	
WAIS-IV Processing Speed Index	91.51 (13.21)	90.10 (15.18)	92.88 (10.93)	F=.22 (1,94)	.639	
CVLT-II 1-5 Learning Total	45.37 (9.93)	43.35 (9.72)	47.39 (9.83)	F=3.25 (1,95)	.075	
CVLT-II SDFR	54 (.96)	67 (.93)	40 (.98)	F=.85 (1,95)	.358	
CVLT-II LDFR	69 (1.13)	86 (1.07)	52 (1.19)	F=.79 (1,95)	.376	
WAIS-IV Digit Span	8.36 (2.59)	8.35 (2.53)	8.38 (2.67)	F=.64 (1,96)	.426	
D-KEFS Trail-Making	8.85 (2.78)	8.73 (2.77)	8.96 (2.81)	F=.02 (1,94)	.879	
Number-Letter Switching	` ,	` ′	` ,	. , ,		
D-KEFS Color Word Inhibition	7.80 (4.04)	7.66 (4.45)	7.94 (3.65)	F=.05 (1,93)	.829	
WCST-64 Total Errors	48.08 (8.90)	48.06 (8.93)	48.10 (8.97)	F=.04 (1,94)	.835	
TOMM Trial 2	47.45 (4.54)	46.69 (5.29)	48.18 (3.58)	-1.65 (98)	.103	
TOMM Retention Trial	46.80 (5.54)	45.94 (6.59)	47.63 (4.20)	-1.53 (98)	.128	
QOLI-B General Life Satisfaction	4.07 (1.30)	4.19 (1.21)	3.96 (1.38)	.86 (95)	.390	

^a Minutes of loss of consciousness from the worst injury reported. ^b All comparisons between cognitive variables were conducted using ANCOVAs controlling for TOMM Trial 2. CPT=Cognitive Processing Therapy; SMART-CPT=Cognitive Symptom Management and Rehabilitation Therapy combined with CPT; TBI=traumatic brain injury; PTSD=posttraumatic stress disorder; PCL-S= PTSD Checklist – Specific Trauma; NSI=Neurobehavioral Symptom Inventory; BDI-II: Beck Depression Inventory - Second Edition; WRAT= Wide Range Achievement Test; WAIS-IV=Wechsler Adult Intelligence Scale – Fourth Edition; D-KEFS= Delis Kaplan Executive Function System; WCST-64=Wisconsin Card Sorting Test – 64 Card Version; TOMM=Test of Memory Malingering; QOLI-B=Quality of Life Interview-Brief Version

Symptom Change

Table 2 presents the relevant MLM model parameter estimates, p values, and effect sizes for each analysis conducted. Estimates of effect sizes are reported as r values (small = 0.10; medium = 0.30; large = 0.50). Both groups showed clinically significant decreases in PTSD and post-concussive symptoms, but with no significant group x time interaction. PCL-S scores dropped by a clinically significant average of 19 points and showed a statistically significant main effect of time, b = -1.26, t(318.83) = -12.47, p < .001, r = .57. However, there was no group x time interaction (p = .085). Similarly, for post-concussive symptom reporting, NSI scores dropped a clinically significant average of 13 points from baseline to follow-up, resulting in a main effect of time, b = -.46, t(62.40) = -4.05, p < .001, r = .46, but no group x time interaction (p = .784). In terms of depression symptoms, the BDI-II dropped a clinically significant average of 11 points and there was a main effect of time, b = -.43, t(54.60) = -5.42, p < .001, r = .59, but no group x time interaction (p = .633).

Quality of Life

There was a main effect of time, but no group or group x time interaction, on the majority of QOLI-B indicators. On the QOLI-B, there was a main effect of time for 'General Life Satisfaction', b = .03, t(70.24) = 2.81, p = .006, r = .32, satisfaction with 'Daily Activities & Functioning', b = .03, t(62.97) = 3.54, p = .001, r = .41, satisfaction with 'Family', b = .03, t(50.36) = 3.24, p = .002, r = .42, and satisfaction with 'Health', b = .02, t(73.40) = 2.68, p = .009, r = .30, but no group x time interactions (all ps > .33). However, for satisfaction with 'Work & School' there was group x time interaction, b = -.05, t(10.41) = -3.51, p = .005, r = .74 such that the CPT-C group expressed greater job satisfaction over the study visits compared to the SMART-CPT group.

Objective Cognitive Functioning

Regarding processing speed, there was no main effect of time, nor group x time interaction (ps > .07) as measured by the WAIS-IV Processing Speed Index. In the domain of attention and working memory, there was a group x time interaction, b = .07, t(67.79) = 2.67, p = .010, r = .31, as measured by WAIS-IV Digit Span Total scaled score, such that attention and working memory improved more over time in the SMART-CPT group than the CPT-C group (see Figure 1). For verbal learning (CVLT-II Trials 1-5 T-score), there was a group x time interaction, b = .32, t(66.19) = 2.74, p = .008, r = .32, showing that verbal learning improved more over time in the SMART-CPT group than the CPT-C group (see Figure 1). For immediate verbal recall (CVLT-II short delay free recall z-score), there was a group x time interaction, b = .03, t(83.05) = 2.18, p = .032, r = .23, in which immediate verbal recall improved more for those in the SMART-CPT group relative to those in the CPT-C group (see Figure 1). For delayed verbal recall (CVLT-II long delay free recall z-score), there was a main effect of time, b = .02, t(73.24) = 2.69, p = .009, r = .30, but no group x time interaction (p = .248).

In terms of executive functioning, for problem solving specifically (WCST-64 Total Errors T-score), there was a significant group x time interaction, b = .27, t(94.78) = 2.38, p = .019, r = .24, such that the SMART-CPT group showed greater improvement over time in problem solving than the CPT-C group (see Figure 1). For cognitive flexibility (D-KEFS Trail Making Number Letter Switching scaled score), there was a main effect of time, b = .08, t(65.59) = 3.93, p < .001, r = .44, but no group x time interaction (p = .830). For inhibition (D-KEFS Color Word Interference Inhibition scaled score), there was a main effect of time, b = .08, t(83.69) = 2.56, p = .012, r = .27, but no group x time interaction (p = .737).

None of the cognitive findings changed when controlling for TOMM retention trial instead of TOMM trial 2. Additionally, when excluding those who performed below cutoff on two of three effort measures at any of the three assessment time points (n = 24; below 45 on TOMM trial 2 or retention or below 15 on CVLT-II forced-choice), all cognitive findings were successfully replicated with the exception of CVLT-II short delay free recall z-score which dropped to a trend for the group by time interaction, b = .02, t(75.50) = 1.69, p = .096, r = .19.

Treatment Satisfaction

As determined by the Client Satisfaction Questionnaire, participants in the SMART-CPT group (M = 29.65) expressed slightly more overall satisfaction with treatment than the CPT-C group (M = 27.86), though the difference was not statistically significant, t(27.52) = -1.78, p = .086. Regarding specific items on the CSQ, those in the SMART-CPT group (M = 3.87) rated "how satisfied are you with the amount of help you received" significantly higher than the CPT-C group (M = 3.43; t(27.58) = -2.48, p = .020), though no other item was differentially endorsed between groups.

Table 2. Estimates for effects of group, time, and group x time interaction

Dependent Variable	(Group		Time			Group x Time		
	b (SE)	p	r	b (SE)	p	r	b (SE)	p	r
Symptom Self-report									
PCL-S	.79 (1.95)	.685	.04	-1.26 (.10)	<.001	.57	.23 (.14)	.085	.10
NSI	86 (2.63)	.745	.04	46 (.11)	<.001	.46	.04 (.15)	.784	.04
BDI-II	3.02 (1.56)	.056	.20	43 (.08)	<.001	.59	.05 (.11)	.633	.07
QOLI-B									
General Life Satisfaction	39 (.25)	.115	.16	.03 (.01)	.006	.32	.01 (.01)	.500	.08
Daily Activities & Functioning	34 (.19)	.078	.18	.03 (.01)	.001	.41	.01 (.01)	.331	.12
Family	.03 (.31)	.929	.01	.03 (.01)	.002	.42	01 (.01)	.385	.12
Health	23 (.22)	.292	.11	.02 (.01)	.009	.30	.01 (.01)	.672	.05
Objective Cognitive Functioning									
WAIS-IV Processing Speed Index	1.23 (2.51)	.625	.05	.27 (.15)	.077	.21	.06 (.20)	.754	.04
WAIS-IV Digit Span Total	61 (.48)	.208	.14	00 (.02)	.813	.03	.07 (.02)	.010	.31
Verbal Learning/Memory									
CVLT-II 1-5 Learning Total	2.79 (2.01)	.168	.14	.14 (.09)	.120	.18	.32 (.12)	.008	.32
CVLT-II SDFR	.19 (.19)	.317	.10	.01 (.01)	.190	.13	.03 (.01)	.032	.23
CVLT-II LDFR	.19 (.21)	.382	.08	.02 (.01)	.009	.30	.01 (.01)	.248	.14
Executive Function									
WCST-64 Total Errors	.34 (1.82)	.851	.02	03 (.08)	.676	.04	.27 (.11)	.019	.24
D-KEFS Trails Switching	20 (.49)	.683	.04	.08 (.02)	<.001	.44	01 (.03)	.830	.03
D-KEFS Inhibition	27 (.77)	.731	.03	.08 (.03)	.012	.27	01 (.04)	.737	.04

PCL-S= PTSD Checklist – Specific Trauma; NSI=Neurobehavioral Symptom Inventory; BDI-II=Beck Depression Inventory – Second Edition; QOLI-B=Quality of Life Interview – Brief Version; WAIS-IV= Wechsler Adult Intelligence Scale – Fourth Edition; CVLT-II=California Verbal Learning Test – Second Edition; D-KEFS= Delis Kaplan Executive Function System; WCST-64= Wisconsin Card Sorting Test – 64 Card Version.

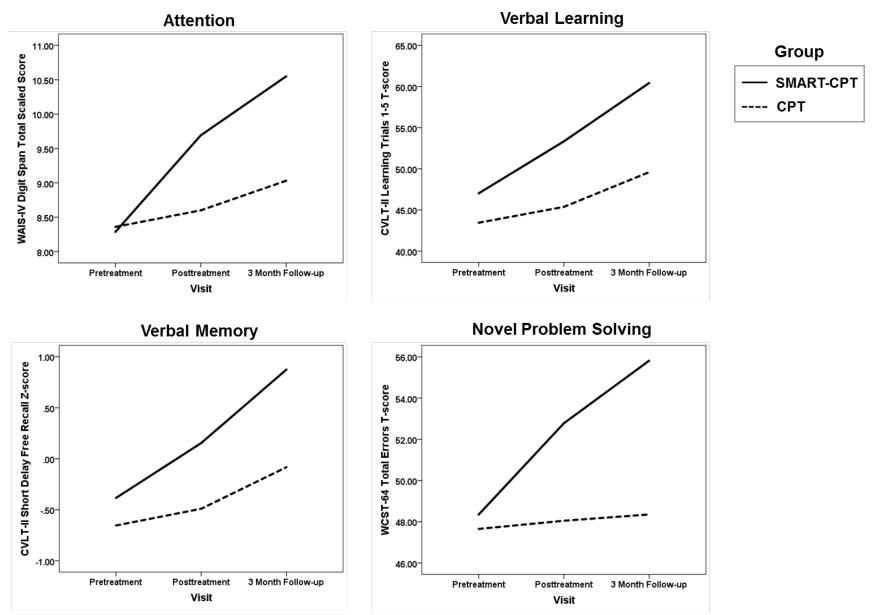


Figure 1

3b. Dissemination of Results:

Dissemination of results began in the second fiscal year and will continue past the period of funding due to lengthy submission and review processes. Consistent with our statement of work, this study has resulted in multiple presentations, talks, and manuscripts. Additionally, a SMART-CPT Treatment Manual is available and sent upon request. For a complete list of manuscripts and presentations, please see section 'Reportable Outcomes' below.

KEY RESEARCH ACCOMPLISHMENTS:

- All regulatory approvals obtained and maintained
- 107 Veterans enrolled in the trial
- 6 published manuscripts; 7 manuscripts under review/in preparation
- 25 presentations
- 1 treatment manual
- Both CPT and SMART-CPT result in clinically significant reductions in PTSD and post-concussive symptomatology and improvements in quality of life.
- SMART-CPT results in additional improvements in the neuropsychological domains of attention/working memory, learning, memory, and novel problem solving and in patient satisfaction.
- SMART-CPT reduces PTSD and neurobehavioral symptoms and also provides added value by improving attention/working memory, learning, memory, and problem solving.

REPORTABLE OUTCOMES:

Manuscripts:

- Jak, A.J. (2017). The Primary Role of Mental Health Treatment in Resolution of Persistent Post-Concussive Symptoms. *Current Treatment Options in Psychiatry*, *4*, 231-40.
- Jurick, S. M., Crocker, L. D., Sanderson-Cimino, M., Keller, A.V., Trenova, L. S., Boyd, B., Twamley, E. W., Rodgers, C. S., Schiehser D. M., Aupperle, R. L., & Jak, A. J. (in press). Contributions to Executive Dysfunction in Operation Enduring Freedom/Operation Iraqi Freedom Veterans with Post-Traumatic Stress Disorder and History of Mild Traumatic Brain Injury. To appear in the *Journal of Head Trauma Rehabilitation*.
- Boyd, B., Rodgers, C., Aupperle, R., & Jak, A.J., (2016). Case Report on the Effects of Cognitive Processing Therapy on Psychological, Neuropsychological, and Speech Symptoms in Comorbid PTSD and TBI. *Cognitive and Behavioral Practice*, 23, 178-83. doi:10.1016/j.cbpra.2015.10.001
- Jak, A.J., Crocker, L., Aupperle, R., Clausen, A., & Bomyea, J. (2016). Neurocognition in PTSD: Treatment Insights and Implications. In: *Current Topics in Behavioral Neurosciences: Behavioral Neurobiology of PTSD*. doi: 10.1007/7854_2016_62
- Jurick, S.M., Twamley, E.W., Hays, C.C., Orff, H.J., & Jak, A.J. (2016). Post-concussive Symptom Over-reporting in Iraq and Afghanistan Veterans. *Journal of Rehabilitation Research and Development*, 53, 571-584.

- Jak, A.J., Aupperle, R., Rodgers, C., Lang, A.J., Schiehser, D., Norman, S.B., & Twamley, E.W. (2015). Evaluation of a hybrid treatment for veterans with comorbid traumatic brain injury and posttraumatic stress disorder: study protocol for a randomized controlled trial. *Contemporary Clinical Trials*, 45, 210-216. doi:10.1016/j.cct.2015.10.009
- Jak, A.J., Crocker, L.D., Jurick, S.M., Boyd, B., Sanderson-Cimino, M., Keller, A., Trenova, L., Thomas, K.R., Aupperle, R., Rodgers, C.S., Lang, A.J., Schiehser, D., Norman, S.B., & Twamley, E.W. (under review). SMART-CPT Treatment for Veterans with Comorbid Posttraumatic Stress Disorder and History of Traumatic Brain Injury: A Randomized Controlled Trial.
- Jurick, S.M., Crocker, L.D., Keller, A.V., Hoffman, S. N., Jacobson, M.W, and Jak, A.J. (under review). The Minnesota Multiphasic Personality Inventory-2-RF in Treatment Seeking Veterans with History of Mild Traumatic Brain Injury.
- Crocker, L.D., Jurick, S.M., Thomas, K.R., Keller, A., Sanderson-Cimino, M., Boyd, B., Rodgers, C., Twamley, E.W., & Jak, A.J. (under review). Worse baseline executive functioning is associated with dropout and poorer response to trauma-focused treatment for PTSD.
- Bomyea, J., Jurick, S.M., Keller, A., Hays, C., Twamley, E.W., Jak, A.J. (under review). Neurobehavioral symptom validity and performance validity in Veterans: Evidence for distinct outcomes across data types
- Crocker, L.D., Jurick, S.M. Hays, C.C., Jak, A.J. (in preparation). The Role of Depression and PTSD Symptoms in Cognitive Functioning in Veterans with a History of Mild Traumatic Brain Injury.
- Jurick, S.M., Crocker, L.D., Sanderson-Cimino, M.E., Keller, A., Trenova, L., Boyd, B., Twamley, E. W., Rodgers, C.S., Schiehser D., Aupperle, R. & Jak, A.J. (in preparation). Relationships between symptom clusters of post-traumatic stress and cognition in Veterans with a history of mild traumatic brain injury.
- Boyd, B., Deford, N., Keller, A., Crocker, L.D., Jurick, S.M., Aupperle, R., Rodgers, C., Lang, A.J., Schiehser, D., Norman, S.B., Twamley, E.W. & Jak, A.J. (in preparation). Rates of homework completion in cognitive processing therapy and treatment outcomes for PTSD.

Presentations:

- Jak, A.J. (Accepted for Presentation). Assessment and treatment of persistent post-concussive symptoms in Veterans: rethinking the role of concussion. Invited CE Workshop to be presented at the 46th Annual Meeting of the International Neuropsychological Society, Washington, D.C.
- Jurick, S.M., Crocker, L. D., Keller, A. V., Hoffman, S. N., Thomas, K. R., Boyd, B., Rodgers, C., Twamley, E. W., & Jak, A.J. (accepted for presentation). Can trauma-focused treatment improve poor neuropsychological performance validity in Veterans with PTSD and history of mTBI? To be presented at the 46th Annual Meeting of the International Neuropsychological Society, Washington, D.C.
- Keller, A.V., Crocker, L.D., Jurick, S.M., Sanderson-Cimino, M., Hoffman, S.N., Merritt, V.C., Twamley, E. W., & Jak, A. J. (accepted for presentation). The Interactive Effects of Traumatic Brain Injury Burden and Cognitive Functioning on Suicidal Ideation in Veterans. To be presented at the 46th Annual Meeting of the International Neuropsychological Society, Washington, D.C.

- Jak, A.J. (2017). Integrating the 'Neuro' and 'Psychology' in the Clinical Presentation of Persistent Post-concussive Symptoms in Veterans. Invited presentation at the American Psychological Association Annual Convention, Washington, D.C., 2017.
- Jak, A.J. (2017). Enhanced cognitive rehabilitation to treat Veterans with Comorbid TBI and PTSD. In K. Judge (Chair), Innovative Intervention Programs for Veterans with Neurological Conditions and Their Families. Symposium presented at the American Psychological Association Annual Convention, Washington, D.C., 2017.
- Jak, A.J., Crocker, L. D., Jurick, S. M., Boyd, B., Sanderson-Cimino, M., Keller, A. V., Trenova, L. S., Aupperle, R., Rodgers, C. S., Lang, A.J., Schieshser, D., & Norman, S., Twamley, E. W. (2017). Neuropsychological outcomes following hybrid treatment for Veterans with comorbid TBI and PTSD. Paper presented at the 45th Annual Meeting of the International Neuropsychological Society, New Orleans, LA.
- Jurick, S. M., Crocker, L. D., Sanderson-Cimino, M., Keller, A. V., Hoffman, S. N., Rauch, A. A., Trenova, L. S., Boyd, B., Schiehser, D., Aupperle, R., Twamley, E. W., Rodgers, C. S., & Jak, A. J. (2017). Contributions to Executive Dysfunction in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) Veterans with Post-Traumatic Stress Disorder and Traumatic Brain Injury History. Poster presented at the 45th Annual Meeting of the International Neuropsychological Society, New Orleans, LA.
- Hoffman, S. N., Jurick, S. M., Crocker, L. D., Steele, N. J., Keller, A. V., Rauch, A. A., DeFord, N. E., Sanderson-Cimino, M., & Jak, A. J. (2017). Patterns of Performance and Symptom Validity Tests in Iraq and Afghanistan Veterans with Mild Traumatic Brain Injury History. Poster presented at the 45th Annual Meeting of the International Neuropsychological Society, New Orleans, LA.
- Keller, A. V., Crocker, L. D., Jurick, S. M., Bomyea, J., DeFord, N. E., Hays, C. C., Twamley, E. W., & Jak, A.J. (2017). The Role of Cognitive Functioning in Suicidal Ideation in Veterans with a History of Mild Traumatic Brain Injury and Comorbid Psychiatric Conditions. Poster presented at the 45th Annual Meeting of the International Neuropsychological Society, New Orleans, LA.
- Jak, A.J. (2016, August). Caregiving for individuals with traumatic brain injury. In L. Brown (Chair), Trauma and caregiving: Complicated situations and solutions. Symposium conducted at the American Psychological Association Annual Convention, Denver, CO.
- Jak, A.J. (2016, August). Benefits of mental health treatment in Individuals with comorbid history of TBI. In P. Uy (Chair), Traumatic brain injury as a chronic health condition. Symposium conducted at the American Psychological Association Annual Convention, Denver, CO.
- Keller, A.V., Jurick, S.M., DeFord, N.E., Sanderson-Cimino, M.E., Crocker, L.D., Rauch, A.A., Hoffman, S.N., Trenova, L.S., Jak, A.J. (2016). Depressive symptom clusters and cognitive functioning in OEF/OIF Veterans with comorbid PTSD/TBI. Poster presented at the 2016 American Psychological Association Annual Convention, Denver, CO.
- Rauch, A.A., Hoffman, S., Jurick, S.M., Keller, A., Sanderson, M., Crocker, L., Johnson, C., Trenova, L., Jak, A.J. (2016). Social functioning and working memory in Iraq and Afghanistan Veterans with a history of mild to moderate TBI and PTSD. Poster presented at the 2016 American Psychological Association Annual Convention, Denver, CO.
- Crocker, L.D., Jurick, S.M., Hays, C.C., Jak, A.J. (2016). The role of Depression and PTSD symptoms in cognitive functioning in Veterans with a history of Mild Traumatic Brain

- Injury. Presented at the 44th annual meeting of the International Neuropsychological Society, Boston, MA.
- Jurick, S.M., Sanderson, M., Crocker, L., Johnson, C., Trenova, L., Keller, A., Rauch, A. & Jak, A.J. (February 2016). Examination of cut scores on the validity subscale of the Neurobehavioral Symptom Inventory in Iraq and Afghanistan Veterans with a history of mild to moderate traumatic brain injury. Presented at the 44th annual meeting of the International Neuropsychological Society, Boston, MA.
- Crocker, L.D., Jurick, S.M., Boyd, B., Rodgers, C.S., Twamley, E.W., Schiehser, D.M., & Jak, A. J. (April, 2015). Treatment of veterans with comorbid PTSD and TBI using a hybrid approach. Paper presented as part of the symposium 'Addressing the needs of combat veterans with co-occurring head injury and mental health symptoms: Clinical trial outcomes for individuals with TBI and psychological distress' at the annual meeting of the Anxiety and Depression Association of America Conference, Miami, FL.
- Jak, A.J., Gregory, A., Orff, H.J., Colón, C., Steele, N., Schiehser, D.M., Delano-Wood, L., Jurick, S.M., & Twamley, E.W. (2015). Neuropsychological performance in treatment seeking OEF/OIF Veterans with a history of mild TBI. Paper presented at the 43rd annual meeting of the International Neuropsychological Society, Denver, Colorado.
- Jurick, S.M., Sanderson, M., Trenova, L., Boyd, B., Schiehser, D., Delano-Wood, L., Aupperle, R., Twamley, E.W., Rodgers, C., & Jak, A.J. (2015). Mental health treatment reduces post-concussive symptoms and symptom over-reporting in Iraq and Afghanistan Veterans. Poster presented at the 43rd annual meeting of the International Neuropsychological Society, Denver, Colorado.
- Jurick, S. M., Hays, C., Orff, H. J., Twamley, E.W., & Jak, A. J. (2014). Post-concussive symptom over-reporting in Iraq and Afghanistan Veterans. Poster presented at the 42nd annual meeting of the International Neuropsychological Society, Seattle, WA.
- Jak, A.J., (2014). Innovations in Assessment and Treatment of Post-Concussive Symptoms in Veterans. Invited presentation at the Frontiers of Brain Health Lunch Lecture Series at the UT Dallas Center for Brain Health, Dallas, TX.
- Jak, A.J., (2014). Traumatic Brain Injury. Invited presentation at the National Association of Drug Court Professionals/Vet Court Con Annual Training Conference, Anaheim, CA.
- Kontos, A.P., Gorgens, K., Uomoto, J., & Jak, A.J. (2014). Active Recovery Strategies for mTBI/Concussion: Evidence-based Treatments and Rehabilitation. Symposium presented at the American Psychological Association Convention, Washington, D.C.
- Jak, A.J. Neuropsychological Assessment and Cognitive Profiles in TBI (2013). "Neuropsychological Assessment and Cognitive Profiles in TBI." Invited Speaker at the VISN 22 Mental Health and PolyTrauma Conference "Bridging the Gap."
- Jak, A.J. (2013). "Comorbid TBI and PTSD in Veterans." Invited Keynote Panel at 18th International Conference & Summit on Violence, Abuse, & Trauma.
- Jurick, S., Jak, A.J., Colon, C., Orff, H., Hays, C., Gregory, A., and Twamley, E., (2013). Cognitive Profiles of Mild to Moderate Traumatic Brain Injury Iraq and Afghanistan Veterans. Poster presented at the International Neuropsychological Society Annual Meeting, Waikoloa, HI.

Other Products:

Jak, A.J., Aupperle, R., Rodgers, C.S., Lang, A.J., Schiehser, D.M., Norman, S.B., Boyd, B., & Twamley, E.W. (2016).SMART-CPT: Cognitive Symptom Management and Rehabilitation Therapy and Cognitive Processing Therapy hybrid Treatment Manual.

CONCLUSION:

In summary, "Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD", has adhered to the tasks outlined in the statement of work, however, we extended the recruitment tasks to accommodate for a drop-out rate that was higher than anticipated. We maintained regulatory compliance and approvals with the VA IRB and the US Army HRPO. Work supported by this award led to 6 published manuscripts, 7 manuscripts under review/in preparation, 25 presentations, and 1 treatment manual, all listed in the Reportable Outcomes of this report. The results of this trial also serve as the basis for a new CDMRP PH/TBI proposal that seeks to add additional modules to SMART-CPT to target pain symptoms as a mechanism to attenuate the high dropout rate of this otherwise efficacious treatment.

Traumatic injuries that lead to mental health conditions and include a history of concussion are complex, and interdisciplinary or multifactorial treatment is recommended. Combining CPT for PTSD symptom reduction with components of CogSMART for neuropsychological symptoms effectively targets a highly prevalent co-morbidity in OEF/OIF/OND treatment seeking Veterans with trauma (both physical and psychological) histories. It does so without negatively impacting satisfaction or treatment retention even though sessions are longer. Treatments and trials related to PTSD and comorbidities are acknowledged gaps identified by the VA/DoD Treatment Guidelines for PTSD and SMART-CPT helps fill that knowledge gap. These data support the use of SMART-CPT, allowing for focus on overlapping etiologies, concurrent treatment of intertwined PCS and PTSD symptoms, and ability to simultaneously address factors that may contribute to persistent symptoms. SMART-CPT results in equivalent mental health and neurobehavioral symptom reduction as compared to standard CPT, but with additional benefit to neuropsychological performance. Additionally, SMART-CPT can be delivered in less time than administering both treatments separately. Because the psychological and fiscal costs of PTSD and TBI are high, (particularly within OEF/OIF/OND Veterans) as are healthcare utilization rates, even small improvements in efficiency of service delivery and retention of Veterans in treatment can result in notable healthcare cost reductions. Augmenting a standard mental health intervention for PTSD with compensatory cognitive strategies is feasible and provides added value to improving attention, memory, and problem solving symptoms while maintaining efficacy of PTSD symptom reduction. Combining therapeutic approaches in the clinical treatment of comorbid PTSD and TBI by enhancing an existing empirically supported PTSD intervention with cognitive rehabilitation principles also can defragment care and significantly improve treatment for this clinically complicated group.

APPENDICES:

Quad Chart attached as a separate document.

Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

Jak W81XWH-11-1-0641

PI: Amy Jak, Ph.D.

Org: Veterans Medical Research Foundation

Award Amount: \$2,075,453

Group

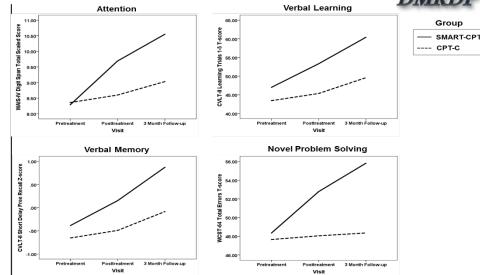
Study Aim(s)

Primary Aim 1: To investigate the efficacy of SMART-CPT in reducing emotional and neurobehavioral symptom severity in veterans with comorbid TBI and PTSD.

Primary Aim 2: To investigate the extent of cognitive changes in veterans with comorbid PTSD and TBI following treatment with SMART-CPT.

Approach

Randomized controlled treatment study to test a modification of Cognitive Processing Therapy (CPT) for PTSD in which CPT is interwoven with compensatory cognitive rehabilitation principles (CogSMART) to create a hybrid treatment, SMART-CPT. The study examined 100 veterans diagnosed with both PTSD and a history of mild to moderate TBI and randomized half to receive standard CPT and half to receive SMART-CPT for 12 weekly sessions. Veterans also received comprehensive symptom, mental health, and neuropsychological assessments at 3 timepoints during the study. The investigation sought to improve treatment outcomes for combat-related psychological health and develop an evidence-based intervention for treatment of comorbid TBI and PTSD.



Timeline and Cost

Activities	12	13	14	15	16	17
Study Start Up						
Recruitment, Enrollment, Assessment, Treatment						
Ongoing recruitment, treatment, data entry						
Data Analysis, Dissemination of Results						
Estimated Budget (\$K)	\$491	\$514	\$530	\$540	XX	XX

Updated: (December 14, 2017)

Goals/Milestones (Refer to previous reports for FY12-15)

FY12 Goals - Study Start Up

FY13 Goals – Recruitment, Enrollment, Treatment, and Assessment

FY14 Goals – Ongoing recruitment, treatment protocol, data entry

FY15 Goals – Ongoing recruitment, treatment protocol, data entry

FY16 Goals - Continued recruitment, Assessments, Treatment

☑ Recruitment/enrolment completed

☑ Assessments

☑ Treatment

FY17 Goals – Analysis, Presentation, Publication, Dissemination

☑ Data Analysis

☑ Dissemination of Results

Comments/Challenges/Issues/Concerns

2nd 1-year NCE to proceed to final stage – data analysis and dissemination; Actual expenditure under budget since hiring was not complete until midway through FY12 and Co-I funding changes in FY13-14

Budget Expenditure to date

Projected Expenditure: \$2,075,453 Actual Expenditure: \$1,909,413